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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

NOTIFICATION DATE	DELIVERY MODE
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04/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/588,131	Applicant(s) TERLIUC, GAD	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 170,171,174-189 and 191-198 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 170,171,174-189 and 191-198 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/26/9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on March 9, 2010, amended claims 170, 189 and 197 and canceled claims 172-173 and 190 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 170-171, 174-175, 177-185, 188-189, 191-194 and 197-198 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,983,165 to Loiterman.

In regard to claim 170, Loiterman discloses an endoscope assembly comprising: a selectably tiltable endoscope head extending along a longitudinal axis and having a first plurality of selectably radially extendible elements 4 associated therewith at at least one first axial location therealong and a second plurality of selectably radially extendible elements 5 associated therewith at at least one second axial location therealong (see Fig. 1); and an endoscope head controller 14 being operative for controlling selectable extension of the first and second pluralities of selectably radially extendible elements for selectable positioning of the endoscope head and selectable tilting of the endoscope head (see Figs. 4-6 and Col. 4, Lines 8-34).

In regard to claim 171, Loiterman discloses an endoscope assembly, wherein the endoscope head controller is operative for controlling selectable extension of the first and second pluralities of selectably radially extendible elements for selectable parallel off-center orientation of the endoscope head (see Figs. 4-6 and Col. 4, Lines 8-34). It is noted that the words “*operative for*” in the claim may be properly interpreted as “capable of,” and “capable of” does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

In regard to claim 174, Loiterman discloses an endoscope assembly, wherein at least one of the first and second pluralities of selectably radially extendible elements comprises a plurality of radially extendible elements distributed generally azimuthally about the endoscope head (see Figs. 2-3 and Col. 3, Lines 48-57).

In regard to claim 175, Loiterman discloses an endoscope assembly, wherein the endoscope head comprises a locomotive endoscope head (see Fig. 1)

In regard to claim 177, Loiterman discloses an endoscope assembly, wherein at least one of the first and second pluralities of selectably radially extendible elements comprises a plurality of selectably inflatable balloons (see Figs. 2-3 and Col. 3, Lines 48-57).

In regard to claim 178, Loiterman discloses an endoscope assembly, also comprising an endoscope body 1 associated with the endoscope head and an instrument channel 9 at least partially extending through the endoscope head and the endoscope body (see Col. 3, Lines 41-47).

In regard to claim 179, Loiterman discloses an endoscope assembly, wherein the endoscope head has a fixed length (see Fig. 1).

In regard to claim 180, Loiterman discloses an endoscope assembly, and wherein the endoscope body interfaces with the endoscope head controller and also comprising an endoscopy system 10, 13, 14 to which the endoscope head controller is connectable (see Fig. 1 and Col. 4, Lines 5-20).

In regard to claim 181, Loiterman discloses an endoscope assembly, wherein the endoscope body includes at least one lumen 7 operative for extension of the radially extendible elements (see Col. 4, Lines 8-10).

In regard to claim 182, Loiterman discloses an endoscope assembly, wherein the first plurality of selectably radially extendible elements comprises at least two independently selectably radially extendible elements (see Figs. 4-6 and Col. 4, Lines 8-34).

In regard to claims 183-184, Loiterman discloses an endoscope assembly, wherein the second plurality of selectably radially extendible elements comprises at least two independently selectably radially extendible elements (see Figs. 4-6 and Col. 4, Lines 8-34).

In regard to claim 185, Loiterman discloses an endoscope assembly, wherein the at least two independently selectably radially extendible elements of the second plurality of selectably radially extendible elements are azimuthally offset with respect to the at least two independently selectably radially extendible elements of the first plurality of selectably radially extendible elements (see Col. 4, Lines 48-50).

In regard to claims 188-189, Loiterman discloses an endoscope assembly, wherein at least one of the first and second pluralities of selectably radially extendible elements comprises a plurality of selectably inflatable balloons (see Figs. 4-6 and Col. 3, Lines 49-56).

In regard to claims 191-194, Loiterman discloses an endoscope assembly, wherein the at least two independently selectably radially extendible elements comprise at least two independently selectably inflatable balloons (see Figs. 4-6 and Col. 3, Lines 49-56).

In regard to claim 197, Loiterman discloses an endoscope positioning method comprising: providing a selectably tiltable endoscope head extending along a longitudinal axis and having a first plurality of selectably radially extendible elements 4 associated therewith at at least a first axial location therealong and a second plurality of selectably radially extendible elements 5 associated therewith at at least a second axial location therealong; and selectably positioning the endoscope head by selectable extension of the first and second pluralities of selectably radially extendible elements; and selectably tilting of the endoscope head by selectable extension of the first and second plurality of selectably radially extendible elements (see Figs. 4-6 and Col. 4, Lines 8-34).

In regard to claim 198, Loiterman discloses an endoscope positioning method, wherein at least one of the first and second pluralities of selectably radially extendible elements comprises a plurality of radially extendible elements distributed azimuthally about the endoscope head and the positioning the endoscope head includes selectable

Art Unit: 3739

extension of individual ones of the plurality of radially extendible elements (see Figs. 2-3 and Col. 3, Lines 48-57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 176 and 186-187 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,983,165 to Loiterman in view of U.S. Patent No. 6,585,639 to Kotmel et al.

In regard to claims 176 and 186-187, Loiterman discloses an endoscope assembly comprising a selectably tiltable endoscope head extending along a longitudinal axis and having a first plurality of selectably radially extendible elements 4 associated therewith (see rejection above) but are silent with respect to wherein at least one of said first and second pluralities of selectably radially extendible elements is axially displaceable with respect to the other. Kotmel et al. teach of an analogous endoscopic apparatus comprising a sheath assembly 200 comprises a flexible tubular body 202 having a first inflatable cuff 204 at a distal end thereof. A Luer or other suitable connector 206 is provided at a proximal end of a flexible tubular body 202, and a separate inflation connector 208 is provided to permit inflation of the cuff 204. The sheath assembly 200 includes additional structure for positioning a second inflatable cuff 210 at an axially spaced-apart location over the exterior of the flexible tubular body

Art Unit: 3739

202. The structure may be a sleeve 212 which is slidable mounted over the outside surface of the flexible tubular body 202. In this way, the sleeve 212 can be translated proximally and distally over the flexible tubular body 202 to permit selective positioning of the second inflatable cuff 210 (see Figs. 13-15 and Col. 11, Lines 40-67). It would have been obvious to one skilled in the art at the time the invention was made to provide the second plurality of extendable elements of Loiterman on a removable sheath, to allow axial displacement between the first and second extendable elements and thus facilitate more effective and efficient positioning of the endoscope within a body cavity as taught by Kotmel et al.

Claims 195-196 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,983,165 to Loiterman in view of U.S. Patent No. 4,040,413 to Ohshiro.

In regard to claims 195-196, Loiterman discloses an endoscope assembly comprising a selectably tiltable endoscope head extending along a longitudinal axis and having a first plurality of selectably radially extendible elements 4 associated therewith (see rejection above) but are silent with respect to an endoscope tool arranged to travel along the instrument channel to a utilization location forward of the endoscope head, the endoscope tool being slidably and sealingly located within the instrument channel; and a fluid endoscope tool positioner for selectably pressurizing the instrument channel for providing fluid driven desired positioning of the endoscope tool along the instrument channel. Ohshiro teaches of an analogous an endoscope assembly wherein when the endoscope is inserted in a body cavity, the balloons 52a and 52b of the inner sleeve 51

Art Unit: 3739

and the balloons 54a and 54b of the outer sleeve 53 are alternately inflated and deflated and the inner sleeve 51 and the outer sleeve 53 are alternately advanced into the body cavity 56. The inner sleeve 51 with deflated balloons 52a and 52b is first inserted into the body cavity 56 up to a position to which the inner sleeve 51 can be inserted comparatively easily. Then, the balloons 52a and 52b provided on the inner sleeve 51 are inflated simultaneously to enlarge the space in the body cavity 56 therearound as shown in FIG. 5. Thus, the insertion of the outer sleeve 53 into the body cavity 56 is facilitated. After the outer sleeve 53 with deflated balloons 54a and 54b has been inserted into the body cavity 56, the balloons 54a and 54b are inflated simultaneously to enlarge the space therearound and the balloons 52a and 52b on the inner sleeve 51 are deflated as shown in FIG. 6. Then, the inner sleeve 51 is further advanced into a deeper part of the body cavity 56. By repeating the above steps, the endoscope can easily be inserted deeply in the body cavity without pain (see Col. 4, Lines 18-65). It would have been obvious to one skilled in the art at the time the invention was made to insert an endoscope tool through the working channel of Loiterman to provide an endoscopic system which can easily be advanced, by a piston-like motion, deep into a body cavity while minimizing pain to a patient as taught by Ohshiro.

Response to Arguments

Applicant's arguments filed March 9, 2010 have been fully considered but they are not persuasive.

Applicant states that Loiterman fails to teach of a selectively tiltable endoscope head controlled by an endoscope head controller. Examiner disagrees. Loiterman

Art Unit: 3739

discloses that each individual aiming balloon is operatively connected to a control tubule or duct 7 located between the inner and outer surface of the tubular member 1. The control ducts 7 are operatively connected to a servo pump 10. The servo pump 10 is operatively electrically connected to an electronic microprocessor based computer 13. The microprocessor based computer 13 is operatively electrically connected to a joy stick mechanism 14. The sets of aiming balloons 4 and 5, duct 7 and servo pump 10 are charged with a suitable fluid or gas for inflation of the sets of aiming balloons 4 and 5, such as, for example, isotonic saline. After the catheter tip 15 is inserted into a vascular system 16 from a peripheral location such as the femoral artery in the groin, the catheter may be aimed in and steered through the vascular system 16. An operator controls the deflection of tip 15 with the joy stick 14. Movement of the joy stick 14 in a direction relative to that desired for catheter tip deflection causes the microprocessor computer 13 to selectively inflate individual aiming balloons by pumping the fluid or gas through the control ducts 7 into the aiming balloons such that the catheter tip 15 is deflected or aimed at the desired branch of the vascular system 16 (see Figs. 4-6 and Col. 4, Lines 8-34). The word "tiltable", by definition means to cause to lean, incline, slope, or slant (see <http://dictionary.reference.com/browse/tiltable>). The endoscope head of Loiterman is clearly taught to be inclined into a desired branch of the vascular system. Furthermore, the inflatable balloons act in a similar fashion to those of the instant invention (see applicant's Fig. 7c) as the proximal balloon 4 and distal balloon 5 are each inflated at different rates, to different volumes to "tilt" the endoscope head in a

desired direction (see Loiterman Fig. 5). As broadly as claimed, Loiterman meets the limitations of the recited claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3739

4/2/10